

10/588911
Confirmation No.
IAP11 Rec'd PCT/PTO 09 AUG 2006

PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

2

of

4

Application Number

Filing Date

First Named Inventor

Makoto Kawai, et al.

Art Unit

Examiner Name

Attorney Docket Number

PC26188A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BOVE, et al., "Weight bearing as a measure of disease progression and efficacy of anti-inflammatory compounds in a model of monosodium iodoacetate-induced osteoarthritis", Osteoarthritis and Cartilage, 2003, pp 821-830, Vol. 11	
		CHUGAI, "Atlixumab Anti-IL-6 receptor antibody - Chugai, Anti-interleukin-6 receptor antibody - Chugai, MRA - Chugai", Biodrugs, pp 349-372, Vol. 17 No. 5	
		CHUGAI, Clinical Trials,, MRA (tocilizumab), Feb 2004	
		CREAMER, et al., "Determinants of Pain Severity in Knee Osteoarthritis: Effect of Demographic and Psychosocial Variables Using 3 Pain Measures", The Journal of Rheumatology, 1999, pp 1785-1792, Vol. 26, No. 8	
		GOLDRING, "The Role of Cytokines as Inflammatory Mediators in Osteoarthritis: Lessons from Animal Models", Connective Tissue Research, 1999, pp 1-11, Vol. 40 No. 1	
		HADLER, "Knee Pain is the Malady - Not Osteoarthritis", Annals of Internal Medicine, 1992, pp 598-599, Vol. 116, No. 7	
		HIRANO, et al., "Biological and Clinical Aspects of Interleukin 6", 1990, pp 443-449, Vol. 11, No. 12	
		HIRATA, et al., "Characterization of IL-6 Receptor Expression by Monoclonal and Polyclonal Antibodies", The Journal of Immunology", 1989, pp 2900-2906, Vol. 143, No. 9	
		HOFFMAN-La ROCHE AG, "Phase II Clinical Study of MRA Shows Significant Clinical Benefit to Children with Systemic-onset Juvenile Idiopathic Arthritis", Media Release, 2003, pp 1-3	
		KIDD, "7.3 Pathogenesis of Joint Pain in Osteoarthritis" Osteoarthritis 2nd Edition, 2003, NY Oxford Press, Inc., pp 185-189	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

10/588911

Confirmation No.

IAP11 Rec'd PCT/PTO 09 AUG 2005

PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 3 of 4 Attorney Docket Number PC26188A

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		LOCKSHIN, et al., "ACR Annual Meeting Report: Anti-IL-6 Receptor Monoclonal Antibody for RA and S-JIA", 2002, American College of Rheumatology	
		MALEMUD, "Cytokines as Therapeutic Targets for Osteoarthritis", Biodrugs, 2004, pp 25-36, Vol. 18, No. 1	
		MASSICOTTE, et al., "Can altered production of interleukin-1p, interleukin-6, transforming growth factor-p and prostaglandin E2 by isolated human subchondral osteoblasts identify two subgroups of osteoarthritic patients", Osteoarthritis and Cartilage, 2002, pp 491-500, Vol. 10	
		MIHARA, et al., "Humanized Antibody to Human Interleukin-6 Receptor Inhibits the Development of Collagen Arthritis in Cynomolgus Monkeys", Clinical Immunology, 2001, pp 319-326, Vol. 98, No. 3	
		SATO, et al., "Reshaping a Human Antibody to Inhibit the Interleukin 6-dependent Tumor Cell Growth", Cancer Research, 1993, pp 851-856, Vol. 53	
		SAITO, et al., " Preparation of Soluble Murine IL-6 Receptor and Anti-Murine IL-6 Receptor Antibodies", The Journal of Immunology, 1991, pp 168-173, Vol. 147, No. 1	
		SIGMA-ALDRICH inc., "ANTI-Rat IgG (whole molecule) Affinity Isolated Antigen Specific Antibody Developed in Goat Adsorbed with Human Serum Proteins", Product Information, 1999	
		SORBERA, et al., " Atlizumab", Drugs of the Future, 2003 pp 315-319, Vol. 28, No. 4	
		SUZUKI, et al., "Anti-murine IL-6 Receptor Antibody Inhibits IL-6 Effects in Vivo", Immunology Letters, 1991, pp 17-22, Vol. 30	
		TAKAGI, et al., "Blockage of Interleukin-6 Receptor Ameliorates Joint Disease in Murine Collagen-Induced Arthritis", Arthritis & Rheumatism, 1998, pp 2117-2121, Vol. 41, No. 12	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

10/588911
Confirmation No.
IAP11 Rec'd PCT/PTO 09 AUG 2006

PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	4	of	4	Attorney Docket Number	PC26188A
-------	---	----	---	------------------------	----------

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		VanZANEN, et al. "Chimaeric anti-interleukin 6 monoclonal antibodies in the treatment of advanced multiple myeloma: a phase I dose-escalating study", British Journal of Hematology, 1998, pp. 783-790, Vol. 102	
		YAMASAKI, et al., "Cloning and Expression of the Human Interleukin-6 (BSF-2/IFNBeta2) Receptor", Science, 1988, pp 825-828, Vol. 241	
		YOSHIZAKI, et al., "IL-6 Blocking Therapy with Humanized Anti-IL-6 Receptor Antibody (MRA) in Rheumatoid Arthritis", Cutting Edge Reports- www.rheuma21st.com, pp 1-9	

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.